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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; comment request

Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval

PROPOSED COLLECTION: Title: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI) (OMB No. 0925-0613). Type of Information Collection Request: Revision. Need and Use of Information Collection: The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug

and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes. Frequency of Response: Up to 16 times per year. Affected Public: Private sector including businesses, other for-profit organizations, and non-profit institutions. Type of Respondents: Investigators, pharmacists, nurses, pharmacy technicians, and data managers. The annualized respondents' burden for record keeping is estimated to require 14,223 hours (see Table 1). There are no capital costs, operating costs, or maintenance costs.

Table 1. Estimates of Annual Burden

Type of Respondents	Form	Number of Respondents	Frequency of Response	Average Time per Response (Hours)	Total Hour Burden
Investigators and Designee for Investigator Registration and DARF	Statement of Investigator	20,112	1	15/60	5,028
	Supplemental Investigator	20,112	1	10/60	3,352
	Financial Disclosure	20,112	1	5/60	1,676
	Drug Accountability Record Form (DARF and DARF-Oral)	3,907	16	4/60	4,167
Totals					14,223

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance

of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles, Hall, RPh, M.S., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, National Cancer Institute, Executive Plaza North, Room 7149, 9000 Rockville Pike, Bethesda, Maryland 20891. Or call non-toll-free number 301-496-5725 or e-mail your request, include your address to: hallch@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: 9/14/2012

Vivian Horovitch-Kelley

NCI Project Clearance Liaison

National Institutes of Health

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